



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,582	05/24/2001	George B. Witman	07917-145001 / UMMC 01-23	4483

7590 06/07/2002
J. PETER FASSE
FISH & RICHARDSON P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 06/07/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/866,582

Applicant(s)
Witman et al

Examiner
Patricia A. Duffy

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1645

DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. The specification lacks a paper copy of the sequence listing and the claims recite genes and polypeptides that have recited corresponding sequence identifier. Full compliance with the sequence rules is required in response to this office action. Failure to fully comply with the sequence requirements in the time period set forth in this office action will be held non-responsive.

Election/Restriction

2. Prior to setting forth the restriction requirement, it is noted out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the method and products rely upon polypeptides, polynucleotides and antibodies which are encoded by different genes and are from different species to such an extent and require non-coextensive searches to such an extent that they are considered

Art Unit: 1645

to lack a substantial structural feature disclosed as being essential to the disclosed utility.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of *Chlamydomonas* particle protein gene 20, classified in class 536, subclass 23.1.
 2. Claims 8, 9, and 16, drawn to *Chlamydomonas* particle protein encoded by gene 20, classified in class 530, subclass 300.
 3. Claims 10-11, drawn to antibodies *Chlamydomonas* particle protein encoded by gene 20, classified in class 530, subclass 388.1.
 4. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of *Chlamydomonas* particle protein gene 27, classified in class 536, subclass 23.1.
 5. Claims 8, 9, and 16, drawn to *Chlamydomonas* particle protein encoded by gene 27, classified in class 530, subclass 300.
 6. Claims 10-11, drawn to antibodies *Chlamydomonas* particle protein encoded by gene 27, classified in class 530, subclass 388.1.
 7. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of *Chlamydomonas* particle protein gene 46, classified in class 536, subclass 23.1.
 8. Claims 8, 9, and 16, drawn to *Chlamydomonas* particle protein encoded by gene 46, classified in class 530, subclass 300.
 9. Claims 10-11, drawn to antibodies *Chlamydomonas* particle protein encoded by gene 46, classified in class 530, subclass 388.1.

Art Unit: 1645

10. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 52, classified in class 536, subclass 23.1.
11. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 52, classified in class 530, subclass 300.
12. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 52, classified in class 530, subclass 388.1.
13. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 57, classified in class 536, subclass 23.1.
14. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 57, classified in class 530, subclass 300.
15. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 57, classified in class 530, subclass 388.1.
16. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 72, classified in class 536, subclass 23.1.
17. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 72, classified in class 530, subclass 300.
18. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 72, classified in class 530, subclass 388.1.
19. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 88, classified in class 536, subclass 23.1.

Art Unit: 1645

20. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 88, classified in class 530, subclass 300.
21. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 88, classified in class 530, subclass 388.1.
22. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 122, classified in class 536, subclass 23.1.
23. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 122, classified in class 530, subclass 300.
24. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 122, classified in class 530, subclass 388.1.
25. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene 139, classified in class 536, subclass 23.1.
26. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene 139, classified in class 530, subclass 300.
27. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene 139, classified in class 530, subclass 388.1.
28. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of Chlamydomonas particle protein gene Che-2, classified in class 536, subclass 23.1.
29. Claims 8, 9, and 16, drawn to Chlamydomonas particle protein encoded by gene Che-2, classified in class 530, subclass 300.

Art Unit: 1645

30. Claims 10-11, drawn to antibodies Chlamydomonas particle protein encoded by gene Che-2 , classified in class 530, subclass 388.1.
31. Claims 1-7 and 18-23, drawn to nucleic acids vectors and host cells of murine particle protein gene 57, classified in class 536, subclass 23.1.
32. Claims 8, 9, and 16, drawn to murine particle protein gene 57, classified in class 530, subclass 300.
33. Claim 16, drawn to a method of screening for compounds that modulates the activity of murine particle protein gene 57, classified in class 435, subclass 7.1.
34. Claims 17-22, drawn to a methods of screening for compounds that modulate the activity of an isolated human particle protein, classified in class 435, subclass 7.1.
35. Claims 23-25, drawn to a methods of screening for compounds that restore activity of a defective or absent human particle, classified in class 435, subclass 7.1.
36. Claims 26-27, drawn to a methods of diagnosing a disorder caused by a defective or absent human particle protein, classified in class 435, subclass 7.94.
37. Claims 28-30, drawn to a methods of treating a disorder caused by a defective or absent human particle protein by administering a nucleic acid, classified in class 514, subclass 44.
38. Claims 31-36, drawn to a methods of treating an infection caused by a pathogen by administering to the subject an effective amount of an agent

Art Unit: 1645

that inhibits the function of the particle protein, classified in class 424, subclass .

4. The inventions are distinct, each from the other because of the following reasons:

5. Groups 1-32 are drawn to different products. The claims of Inventions 1, 4, 7, 10, 13, 16, 19, 22, 25, 28 and 31 are drawn to different genes encoding different particle proteins, those of Inventions 2, 5, 8, 11, 14, 17, 20, 23, 26, 29 and 32 are drawn to different particle protein encoded by different genes and that of Inventions 3, 6, 9, 12, 15, 18, 21, 24, 27 and 30 to antibodies that bind the different particle proteins. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities that are derived from different genes, encode different gene products or bind the different gene products. The search for one gene or its gene product would not reveal art on the other genes. As such the genes, gene products and antibodies are distinct as claimed.

6. Inventions 33-38 are drawn to different methods. The methods of Groups 33-38 rely on patentably distinct genes or gene products as discussed in above, have different method steps and have different goals as evidenced by the preambles of the methods. As such, the methods are distinct each from the other.

7. Inventions (3, 6, 9, 12, 15, 18, 21, 24, 27 or 30) and (36 or 38) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody could be used to purify the polypeptide or administered as an imaging agent.

Art Unit: 1645

8. Inventions (2, 5, 8, 11, 14, 17, 20, 23, 26, 29 or 32) and (33, 34 or 35) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in materially different methods of using that product such as in a method of treatment, a method of making an antibody or a method of detecting binding sites or as an imaging agent in an in vivo method of imaging. As such, the product is distinct from each of the methods.

9. Inventions (1, 4, 7, 10, 13, 16, 19, 22, 25, 28 or 31) and (37) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used in materially different methods of using that product such as in a method of treatment, a method of making the polypeptide or in a method of detecting expression by hybridization. As such, the product is distinct from the method.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1645

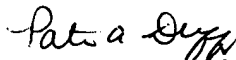
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
June 6, 2002


Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: claims not in compliance

Applicant Must Provide:

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY